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|---|
| SCHNIZER, HOLLY G |

| ART UNIT | PAPER NUMBER |
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| 1653 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

| Office Action Summary | Application No. 09/809,827 | Applicant(s) ANDERSON ET AL. | |
|---|---|---|---|
| | Examiner Holly Schnizer | Art Unit 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-112* is/are pending in the application.

4a) Of the above claim(s) *1-41,45,46 and 58-112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *42-44 and 47-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *6* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## *DETAILED ACTION*

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5 and 27, drawn to recombinant expression constructs encoding an ANT1 polypeptide, classified in class 435, subclass 320.1.

II. Claims 6 and 28, drawn to recombinant expression constructs encoding an ANT2 polypeptide, classified in class 435, subclass 320.1.

III. Claims 7 and 29, drawn to recombinant expression constructs encoding an ANT3 polypeptide, classified in class 435, subclass 320.1.

Claims 1-4, 8-26, and 30-41 link Groups I-III. These linking Claims will be examined with respect to the subject matter of the Invention of Groups I, II, or III, if one of these Groups is elected.

IV. Claims 42-44 and 47-57 drawn to ANT1 polypeptide, classified in class 530, subclass 300.

V. Claim 45, drawn to ANT2 polypeptide, classified in class 530, subclass 300.

VI. Claim 46, drawn to ANT3 polypeptide, classified in class 530, subclass 300.

VII. Claim 60, drawn to a method of determining the presence of an ANT1 polypeptide in a sample, classified in class 435, subclass 7.1 .

VIII. Claim 61, drawn to a method of determining the presence of an ANT2 polypeptide in a sample, classified in class 435, subclass 7.1 .

IX. Claim 62, drawn to a method of determining the presence of an ANT2 polypeptide in a sample, classified in class 435, subclass 7.1 .

Claims 58-59, 63-74 link Groups VII-IX. These linking Claims will be examined with respect to the subject matter of the Invention of Groups VII-IX, if one of these Groups is elected.

X. Claims 75-84 and 104 drawn to a method for identifying an agent that binds to an ANT polypeptide and an assay plate for high throughput screening of candidate agents that bind ANT polypeptide, classified in class 435, subclass 7.1.

XI. Claims 85-103 and 107-111, drawn to an ANT ligand, classified in class 530, subclass 300.

XII. Claims 105-106 drawn to a method of targeting a polypeptide to the mitochondrial membrane, classified in class 435, subclass 317.1.

XIII. Claim 112, drawn to a method of treatment comprising administering a pharmaceutical composition comprising an ANT ligand, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the genes encoding ANT1, ANT2, and ANT3 are distinct and encode proteins having different structures, functions, and which are expressed in different tissues. For example, ANT1 is expressed in heart and skeletal muscle; ANT2 appears to only be expressed in neoplastically transformed cells with high glycolytic rates, in tumors, and tumoral cells; and ANT3 is ubiquitously expressed (Giraud et al. J. Mol. Biol. (1998) 281: 409-418, see p. 409, col. 2; ref. BH in IDS filed 3-16-01 as Paper No. 6). Moreover, while ANT1 and ANT3 export ATP synthesized in the mitochondria to the cytosol, ANT2 appears to translocate glycolytic ATP synthesized in the cytosol, to the mitochondrial matrix (see Giraud et al. p. 413, Col. 2). Because the ANT protein isoforms are expressed in different tissues and have different structures and functions, the polynucleotides encoding them are independent and distinct, one from the other, and could be used for different purposes and have different effects.

The inventions of Groups IV-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ANT1, ANT2 and ANT3 polypeptides are distinct are unrelated for the reasons stated in the preceding paragraph. ANT1, ANT2 and ANT3 proteins have different structures, functions, and are expressed in different tissues. Because the ANT protein isoforms are expressed in different tissues and have different

structures and functions, they are independent and distinct, one from the other, and could be used for different purposes and have different effects.

The inventions of Groups I-VI and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the expression constructs and host cells of Inventions I-III, the polypeptides of Inventions IV-VI, and the ligands of Invention XI have different biological structures and different functions. In addition, subject matter of each Group is not coextensive and thus the search for each would constitute a serious burden upon the examiner. For example, the expression constructs of Group I would require consideration of its use for processes other than the production of the protein, such as nucleic acid hybridization assay and the protein would required searches of literature wherein the protein was isolated from its source rather than recombinantly produced using the polynucleotide. Thus, Groups I-III require considerations which are not required in the search for proteins of Groups IV-VI and Groups IV-VI require considerations which are not required in the search for the polynucleotides of Groups I-III. Likewise, the polypeptides of Groups IV-VI have different functions and are used for different purposes than the ligands of Group XI.

The expression vectors of Groups I-III are unrelated to the methods of Groups VII-X and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the

expression vectors of Groups I-III are not made by nor used in the protein binding assays of Groups VII-X or the method of treatment using an agent that binds ANT of Group XIII.

Inventions I-III and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the expression vectors of Groups I-III can be used in a method of making the polypeptides or in hybridization assays, which are materially different processes than the method of targeting the ANT polypeptide to the mitochondrial membrane of Invention XII.

The ANT polypeptides of Groups IV-VI are unrelated to the methods of Groups VII-IX and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polypeptides of Groups IV-VI are not made by nor used in the method of screening using an ANT ligand of Groups VII-IX or the method of treatment using an agent that binds ANT of Group XIII.

Inventions IV-VI are related to the methods of Groups X and XII as product and process of use. The inventions can be shown to be distinct if either or both of the

following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Groups IV-VI can be used in a method of making an antibody or in activity assays, which are materially different methods than the protein binding assays and method of treatment using an ANT ligand of Groups X and XIII.

The ANT ligands of Group XI are unrelated to the methods of Groups X and XII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ligands of Group XI are not made by nor used in the method of screening using an ANT polypeptide of Group X or the method of targeting an ANT polypeptide to the mitochondrial membrane of Group XII.

The ligand of Invention XI is related to the methods of Inventions VII-IX and XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ligand of Invention XI could be used in a method of inhibiting the activity of the ANT polypeptides, which is materially different than the method of screening for an ANT polypeptide of Groups VII-IX or the method of treatment of Group

XIII. In addition, the ligand could be used in a method of diagnosis, which is materially different from the methods of screening and treatment of Inventions VII-IX and XIII.

The methods of Groups VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the ANT polypeptides are expressed in different tissues and have different structures and functions. Therefore, the different screening methods could not be used together and each method would have different endpoints since each would likely bind ligands of differing structure.

The methods of Inventions VII-X, XII, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions VII-X, XII, and XIII are materially different each from the other because each is practiced with materially different process steps, technical considerations, and reagents and each is practiced to accomplish a distinct goal.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has

prima facie shown a serious burden of search (see MPEP § 803). Therefore, the initial requirement of restriction for examination purposes as indicated is proper.

During a telephone conversation with Stephen Rosenman on June 18, 2003, a provisional election was made without traverse to prosecute the invention of Group IV, claims 42-44 and 47-57 drawn to ANT1 polypeptides. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-41, 45-46, and 58-112 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Status of the Claims***

Claims 1-112 are pending. Claims 1-41, 45-46, and 58-112 are withdrawn from further consideration as being drawn to non-elected subject matter. Claims 42-44 and 47-57 will be examined on the merits in this Office Action.

***Sequence Compliance***

The disclosure is objected to because of the following informalities: There are no sequence identifiers for the sequences listed in Figures 1A, 1B, and 2. Sequence information in the drawings must still be included in a "Sequence Listing" and the sequence identifier ("SEQ ID NO:X") must be used in the drawings or the Brief Description of the Drawings (see 37 C.F.R. 1.821 and MPEP 2429, 22nd paragraph). Correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43-45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is unclear as to the scope of the claim in light of dependent Claims 44-45. As presently written, Claim 43 appears to encompass full-length ANT2

polypeptides. However, Claims 44-45, dependent from Claim 43, include variants or fragments thereof. A proper dependent claim must include every limitation of the parent claim (MPEP 608.01(n)). A test as to whether a claim is a proper dependent claim is that it shall not be infringed by anything that would not also infringe the basic claim (MPEP 608.01(n)(II)). Therefore, Claim 43 is unclear as to whether it encompasses variants and fragments of an ANT2 polypeptide (in which case Claims 44-45 would be proper dependent claims) or whether it does not encompass variants or fragments of an ANT2 polypeptide (in which case Claims 44-45 would be improper dependent claims because they are broader (the dependent claim could be infringed by a disclosure of a variant which would not infringe the independent claim)).

Claims 44-45 are indefinite because, due to the ambiguity of the scope of Claim 43, the claims are unclear as to whether they are improper dependent claims or not. In the present Office Action, Claim 43 has been considered to encompass variants and fragments of ANT2 (see prior art rejection under Adrian et al. below). If this is a broader interpretation of Claim 43 than intended, then dependent Claims 44-45 should be amended to delete "variants or fragments thereof" or rewritten as independent claims to avoid improper dependency. Correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Marzo et al. (Science (Sept. 25, 1998) 281(5385): 2027-2031 ; ref. CG in IDS of Paper No. 6).

Marzo et al. disclose a purified (isolated) human ANT2 protein (p. 2029, Col. 1, lines 9-32, Fig. 2C, Fig. 4). Marzo et al. states that the ANT polypeptide was purified to greater than 95% homogeneity (p. 2029, Col. 1, lines 29-32). The ANT proteins disclosed in Marzo et al. are considered variants and fragments of a recombinant ANT1 polypeptide.

Claims 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Adrian et al. (Mol. Cell. Biol. (1986) 6(2): 626-634; ref. AH of IDS of Paper No. 6).

Adrian et al. disclose the expression of fusion proteins comprising *Saccharomyces cerevisiae* ADP/ATP translocator (ANT) proteins of various lengths (see p. 631, Fig. 5) and the enzyme β-Galactosidase in an investigation of what amino acids are important in targeting the protein to the mitochondrial membrane. The yeast ANT proteins described by Adrian et al. are considered variants of recombinant human ANT1 and are considered to be isolated (see Fig. 6).

Claims 43-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallace et al. (U.S. Patent No. 6,013,858).

Wallace et al. disclose the synthesis of an ANT1 peptide fragment for the use in making antibodies to ANT1 (Col. 16, lines 60-67). The isolated ANT1 fragment of Wallace et al. is considered patentably indistinguishable from the fragment of a recombinant ANT1 encompassed by Claims 43-44.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 42-44, 47-50, 52-55, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adrian et al. (Mol. Cell. Biol. (1986) 6(2): 626-634; ref. AH of IDS of Paper No. 6) in view of Fiore et al. (Biochimie (Feb. 1998) 80: 137-150; ref. BG of IDS of Paper No. 6) and Marzo et al. (Science (Sept. 1998) 281 : 2027-2031).

Adrian et al. disclose the expression of fusion proteins comprising *Saccharomyces cerevisiae* ADP/ATP translocator (ANT) proteins of various lengths (see p. 631, Fig. 5) and the enzyme β-Galactosidase in an investigation of what amino acids are important in targeting the protein to the mitochondrial membrane. The study reveals that several of the fusion proteins were delivered to the mitochondria (see p. 30, Col. 2, lines 23-30, and p. 631, Table 1). The yeast ANT proteins described by Adrian et al. are considered variants of ANT1. The fusion partner β-Gal has an affinity to a ligand that is an antibody to β-Gal.

Adrian et al. do not teach that the ANT proteins were ANT1 proteins.

Fiore et al. provides a review of mitochondrial ADP/ATP carrier proteins (also known as ANT proteins) and evidence that the ANT proteins are very well known in the art. Figure 1 of Fiore et al. provides an amino acid sequence alignment of the known ANT proteins including the sequence of human ANT1 (referred to as HuAnc1 (see Fig. 1 and Table 1).

Marzo et al. shows that at the time of the invention, the skilled artisan was able to recombinantly express human ANT2 (see p. 2031, citation 22) and to isolate highly purified ANT2 (p. 2029, Col. 1, lines 29-32).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to express ANT2 protein using the amino acid sequences disclosed in Fiore et al. as a fusion protein as taught in Adrian et al. One of ordinary skill in the art would have had a reasonable expectation of success in the recombinant expression of an ANT1 fusion protein since Adrian shows the successful expression of

a fusion protein with the yeast adenine nucleotide translocator and Marzo et al. shows the successful expression of human ANT2. One having ordinary skill in the art would have been motivated to substitute ANT1 instead of the disclosed yeast ANT in order to study the mitochondrial localization sequences in the ANT1 polypeptide. Characterization of animal and human ANT proteins is essential to the development of diagnostic and treatment tools because as taught in Fiore et al. (p. 146, Col. 2), these proteins have a central role in cellular energy metabolism and it is likely that dysfunction of these proteins is involved in mitochondrial disorders. In this respect, expression of ANT1 would be especially desirable given the knowledge that there is increased expression of ANT1 in the muscle of patients with myoclonic epilepsy associated with ragged-red fibers and myopathy, encephalopathy, lactic acidosis and stroke-like episodes (see Fiore et al. p. 146, Col. 2, 2nd paragraph of 2nd full paragraph).

Claims 51 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adrian et al., Fiore et al., and Marzo et al., as applied to claims 42-44, 47-50, 52-55, and 57 above, and further in view of Rosenberg (Protein Analysis and Purification: Benchtop Techniques (1996) Birkhauser, Boston, pp. 335-347).

The teachings of Adrian et al., Fiore et al., and Marzo et al. have been described above. Adrian et al. also notes that the large β-Gal protein may interfere with the function of the mitochondrial delivery signals of the β-Gal-translocase fusion protein (p. 630, col. 2, starting at line 36).

Adrian et al., Fiore et al., and Marzo et al. do not teach making a fusion protein wherein the translocase is cleavable by a protease and separable from the fusion partner.

However, Rosenberg shows that it is standard in the art to construct fusions between a protein of interest and an enzyme (i.e. β-Galactosidase (p. 336, lines 3-6 and section titled "Expression and Purification of lacZ and trpE Fusion Proteins") or an affinity tag. Rosenberg teaches that using β-Gal as the fusion partner provides an advantage because antibodies to β-Gal can be used to affinity purify the fusion protein. Rosenberg also teaches that a protease cleavage site can easily be engineered into the fusion so that the fusion partner can be separated from the protein of interest after purification (see p. 344, Section 11.15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make a fusion protein between ANT1 and an enzyme wherein the enzyme sequence is cleavable by a protease and separable from ANT1 since Rosenberg shows that procedures for making such a protein are standard in the art. One of ordinary skill would have been motivated to do so in furthering the studies of Adrian et al. because Adrian et al. suggests that the fusion partner may be interfering with the mitochondrial localization sequences.

***Conclusions***

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
June 24, 2003

CHRISTOPHER S. F. LOW
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